PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Robert J. MEDOFF

Serial No.: 10/821,643 Group No.: 3775

Filed: April 9, 2004 Examiner: Swiger III, James L.

For: FRACTURE FIXATION SYSTEM INCLUDING BUTTRESS PIN AND POST WASHER

Attorney Docket No.: U 015145-3

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

I, Robert J. Medoff, do hereby declare:

1. I am the inventor of the subject matter described and claimed in the above application. I make this declaration in support of this application.

2 I consider myself to be skilled in the art of orthopedic medicine and apparatus by reason of my education and experience as shown on the curriculum vitae attached herewith as Exhibit I.

3. I am the patentee or co-patentee of the patents shown on the list attached herewith as Exhibit II.

4. In the aforesaid aplication 10/821,643, the Examiner has rejected the claims on the

combination of Medoff (US Patent No. 5,709,682) in view of Laboreau (US Patent No. 5,662,655).

5. I am the inventor of the aforesaid Medoff patent and am familiar with its content. I have studied the content of the Laboreau patent and am also familiar with its content.

6. The Examiner considers that Medoff discloses an implant comprising a single wire having a U-shaped bend (for example top view Fig. 2) defining a first region, with opposite legs extending from the U-shaped bend and are parallel, wherein said legs have distal ends (49) that are bent away (also, 5) and are capable of buttressing a surface of a bone (see Fig. 3). This portion of the legs comprise a second portion, aside from a first portion (approx, 41, which lies in the same plane as the U-shaped bend), wherein the second portion lies outside the first plane of the first portion. The legs are considered parallel to one another and the legs are of equal length in the view of Fig. 2. Medoff also discloses a pin in combination with a washer (6, Fig. 6) which can assist in holding the pin legs in relation to another, or alternatively, assist in holding or securing the pin to a bone (with an alternative pin 4). The implant of Medoff further disclose a bent portion (approx 41) that connects the two portions out of plane. The Examiner considers that Medoff discloses the claimed invention except for a region extending from the U-shaped bend which is a second region in proximity to the distal end, in which the spacing of the legs is different, or wherein the length of the legs in the distal region is unequal. Laboreau discloses a single piece implant device (see Fig. 2) that has two regions, one in proximity of the U-shaped bend, and a second region in proximity to the second region, and also has legs of different lengths (13/14) due to the various adjustments from the first region. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Medoff having at least a region extending from the U-shaped bend which is a second region in proximity to the distal end, in which the spacing of the legs is different, or wherein the length of the legs in the distal region is unequal in view of Laboreau so that the device can be better fit and be secured to, differing

sizes and shapes of bone so that adequate support can be provided for recovery.

7. I respectfully disagree for the following reasons.

First, the implant of Laboreau is a staple. It is not in two planes, and it is an implant in which the mechanics of the implant are to prevent the two legs from separating in order to hold the fracture site closed. In this regard, the legs and the metal bridge between them have to be of sufficient strength to prevent the legs from being spread apart. The offset nature of the bridge is to conform to the surface contour of the bone from one fragment to another. In contrast, the offset buttress pin in the application is loaded axially (or longitudinally) so that the line of force is in line with the long axis of the U-shaped member. There is essentially no force that causes the legs to diverge. The implant does not need to be bulky and strong to resist opening up, which is important for the site of application at the wrist where the bulk of a strong implant will lead to tendon irritation and rupture.

Furthermore, the offset in the buttress pin of the application is in the length of the legs (in order to contour to the geometry of the joint surface) or in the width of the U-shaped portion of the implant (in order to match the width of the bone as you go from proximal to distal. The first length change is at 90 degrees to the U-shaped portion of the implant and would have nothing to do with the device of Laboreau. The second issue (changing the width of the U-shaped portion) has to do with the fit of the U-shaped portion as it courses longitudinally along the bone. Since the implant of Laboreau has the U-shaped portion at 90 degrees to the long axis of the bone, the change in width is for a totally different purpose. Moreover, the change in width is in a totally different plane than the application of the external load; therefore I think this is not an obvious inventive step.

As far as the hairpin of Gasper is concerned, I am at a loss how he can see any similarity of function. The double bends in the hat pin are not at different lengths or positions so would appear to have no influence on a patent based on the offset nature of the wire form.

Finally, I can state that I have used the wire forms referenced in Patent No. 5,709,682 longer than anyone in the world, and it took me years before I recognized the issue that

required an offset buttress pin as a solution. I have been fully aware of the type of staple shown, and I think as the world expert on wire forms I can unequivocally state that this is not 'obvious to one skilled in the art'.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 8-10-10

Robert J. Medoff

EXHIBIT I

Brief Curriculum Vitae
Robert J. Medoff, M.D.
Oct 2008

Name:	Robert J. Medoff, M.D.
Home Address:	159 Ku'ukama Street Kailua, Hawaii 96734 808-262-8752
Business Address:	30 Aulike Street, Suite 506 Kailua, Hawaii 96734 808-261-4658
	46-001 Kamehameha Hwy, Suite 402 Kaneohe, Hawaii 96744 808-235-6474
Birthdate:	1954
Birthplace:	Philadelphia, Pennsylvania
Education:	
Undergraduate:	University of Pennsylvania Philadelphia, Pennsylvania B.A. / Physics, 1976 September 1972
	Varsity Letter / Sailing, 1975
Medical School:	University of Pennsylvania Philadelphia, Pennsylvania M.D., 1979
Residencies:	General Surgery University of Hawaii Integrated Surgical Residency Honolulu, Hawaii June 1979 - June 1981
	Orthopaedic Surgery Campbell Clinic 869 Madison Avenue Memphis, Tennessee 38104 January 1982 - December 1984

Hospital appts, present:

Shriner's Hospital for Crippled Children, Honolulu Unit
Courtesy staff
1310 Punahou Street
Honolulu, Hawaii 96826
April 1986 - present

The Queen's Medical Center
Consulting staff
1301 Punchbowl Street
Honolulu, Hawaii 96813
July 1986 - present

Tripler Army Medical Center
Consulting staff
Honlulu, Hawaii
August 1988 - present

Castle Medical Center
Active staff
Kailua, Hawaii
September 1989 - present

Current academic appt:

John A Burns Scholl of Medicine
University of Hawaii
Assitant Clnical Professor of Orthopaedic Surgery
Honolulu, Hawaii
1986 – present

Publications:

Medoff R. Use Of Standard X-rays And Classification Systems In Guiding Treatment. In Fractures and Injuries of the Distal Radius and Carpus. Ed David Slutsky and Lee Osterman, Elseveir, in print 2009.

Medoff R. Distal Radius Fractures: Classification and Management . in Rehabilitation of the Hand and Upper Extremity, 6th Edition. ed Osterman, et al., in print.

Medoff R. : Fragment-Specific Fixation of Distal Radius Fractures. In Operative Techniques in Orthopaedic Surgery, ed Thomas Hunt, Lippincott, in print.

Medoff, R. (May 2008). The Fractured Wrist (DVD-ROM) Virtual Fellowship Interactive Multimedia Program. American Academy of Orthpaedic Surgeons. Steinman S, Ring D, Ladd A ed.

Medoff R. Fragment-Specific Fixation of Distal Radius Fractures Atlas of the Hand Clinics: 11(2), 163-174, Sep 2006.

Medoff, R. (2006). Fragment Specific Fixation of Distal Radius. Wrist and Elbow Reconstruction & Arthroscopy; A Master Skills Publication. T. Trumble and J. Budoff. Rosemont, American Society for Surgery of the Hand: 183-192.

Medoff, R. (2006). Plating of Distal Radius Fractures. Wrist and Elbow Reconstruction & Arthroscopy; A Master Skills Publication.

T. Trumble and J. Budoff. Rosemont, American Society for Surgery of the Hand: 163-182.

Benson, L., Medoff, R. (2006). Fragment Specific Fixation of Distal Radius Fractures. Injuries to the Distal Radius and Carpus. D. Slutsky and L. Osterman. Elsevier: (in print)

Medoff, R. (2006). Radiographic Evaluation and Classification of Distal Radius Fractures. Injuries to the Distal Radius and Carpus. D. Slutsky and L. Osterman. Elsevier: (in print)

Medoff, R. (2007). Fragment Specific Fixation of Distal Radius Fractures. Operative Techniques in Hand Surgery. T. Hunt. Lippincott, Williams, and Wilkins: (in print)

Chapter: Fragment Specific Fixation
In: Atlas of Hand Clinics
Elsevier (in print)

Essential Radiographic Evaluation for Distal Radius Fractures
Hand Clinics, 2005 21(3), 279-288

Open Reduction and Immediate Motion of Intra-articular Distal Radius Fractures With a Fragment-Specific Fixation System, Medoff, RJ, Kopylov, P. Arch Am Acad Orthop Surg 1999: 2; 53-61

Medoff RJ, Kopylov P. Immediate internal fixation and motion of comminuted distal radius fractures using a new fragment specific fixation system. Orthopaedic Transactions 1998-1999; 22(1): 165.

Marumoto JM, Mitsunaga MM, Richardson AB, Medoff RJ, Mayfield GW.
Late patellar tendon ruptures after removal of the central third for anterior cruciate ligament reconstruction. A report of two cases. Am J Sports Med. 1996 Sep-Oct;24(5):698-701.

Axial Compression Screw
in Campbell's Operative Orthopaedics
Eighth Edition
pgs 900-901, pgs 907-909

section on Allograft Ligament Reconstruction
in Campbell's Operative Orthopaedics
Seventh Edition

Medoff, R.J., Maes, K.: Axial Compression Screw, A New Implant for Unstable Trochanteric Fractures of the Hip, JBJS, Sep 91

Albertson KS, Medoff RJ, Mitsunaga MM.
The use of periosteally vascularized autografts to augment the fixation of large segmental allografts.
Clin Orthop Relat Res. 1991 Aug;(269):113-9.

Medoff, R.J.: Injuries to the Hip in Athletes.
Annals of Sports Medicine, 3(2): 73-76, 1987

Medoff, R.J.: Soft Tissue Healing
Annals of Sports Medicine, 3(2): 67-70, 1987

Medoff, R.J.: Insertion of Distal Screws in
Interlocking Nail Fixation of Femoral Fractures
J Bone J Surg, 68A: 1275-1277, Oct 1986

Medoff, R.J.; Medskar, L.R.; Headley, S.L.;
Fortune, H.T.: Additional 1+ States in 20F
Physical Review, 14: 1-3, July 1976
(Supported by grant from National Science Foundation)

Ginsberg, M.D., Medoff, R.J., and Reivich, M.:
Heterogeneities of Regional Cerebral Blood Flow in
Hypoxic-Ischemic Rats
Stroke, 7(2): 132-134, March-April 1976

Course director:

The Wrist Injury Course: from Trauma to Rehabilitation.
Sponsored by Univ of Hawaii, Sheraton Maui Resort
Oct 31 – Nov 2, 2008.

Treatment of Wrist Injuries, Advanced Surgical Techniques
Sponsored by Univ of Hawaii
Haleiwa, Hawaii
Oct 15-17, 2005

Current Options in the Treatment of Wrist Fractures
AAOS Orthopaedic Learning Center, Rosemont, IL
May 14-15, 2004

Advanced Surgical Treatment of Injuries of the Wrist
Sponsored by Univ of Hawaii
Kauai, Hawaii
Nov 7-9, 2003

Current Options in the Treatment of Distal Radius Fractures
Berger, R, Medoff, RJ
AAOS Orthopaedic Learning Center
Sep 20-21, 2002

Advanced treatment of Wrist Injuries
Medoff, RJ, Ladd, A
Grand Cayman Island Nov 30-Dec 2 2001
CME accredited 17.5 hrs

Wrist injury treatment for the 21st century
Medoff, RJ, Ladd, A
Grand Cayman Island, Nov 3-5 2000
CME accredited 17.5 hrs

Treatment of Distal Radius Fractures, Advanced Surgical Techniques Course
Medoff, RJ, Ladd, A Course directors
Maui, Hawaii, May 1999

Hawaii Orthopaedic Association Annual Spring Symposium
Meeting Chairman
May 1993

Previous Job Experience:

Computer Programmer
Cerebrovascular Research Laboratory
University of Pennsylvania
Philadelphia, Pennsylvania
1971-1979

Prior clinical/professional practice:

Straub Clinic and Hospital, Inc.
888 South King Street
Honolulu, Hawaii 96813
(808)522-4000
January 1986 - May 1990

The Campbell Clinic
869 Madison Avenue
Memphis, Tennessee 38104
Clinical Instructor/Orthopaedic Staff/Attending Trauma Staff
January 1985 - January 1986

Elvis Presley Regional Trauma Center
Attending Staff
Memphis, Tennessee
Attending Staff January 1985 - January 1986

Previous Team Physician:

Rhodes (Southwestern) College
Team Physician Football Team
Memphis, Tennessee
1985

Memphis State University
Assistant Team Physician
Memphis, Tennessee
1985

Old Number Seven Rugby Team
Team Physician
Memphis, Tennessee
1985

ILH Football League (7 schools)
Team Physician
Honolulu, Hawaii
1986 - 1990

Consulting physician

University of Hawaii Department of Athletics
Honolulu, Hawaii
1986 - 1990

Team physician
Rainbow Classic National Intercollegiate
Basketball Conference
Honolulu, Hawaii
December 1987

Academic Appointments:
Prior:

University of Tennessee Center for the Health Sciences
Memphis, Tennessee
Clinical instructor in Orthopaedic Surgery
1985

Director and Founder Soft Tissue Allograft Bank
University of Tennessee/Campbell Clinic/University of Tennessee
Memphis, Tennessee
1985

Founder and Director Hawaii Allograft Bank
Honolulu, Hawaii
1986 - 1990

Tripler Army Medical Center Orthopaedic Residency
Teaching Staff
Honolulu, Hawaii
1988 - present

Shriner's Hospital Teaching Staff
Honolulu, Hawaii
1986 - present

Research Experience:

Recipient of Resident Research Fellowship by
Orthopaedic Research and Education Foundation, 1984
Research in ligament and soft tissue healing with
electromagnetic fields

Clinical research in allograft use for anterior
cruciate repair

Axial compression screw, design and biomechanical
testing starting in 1984;
clinical testing started in 1988

Hawaiian Supracondylar Device
Design, biomechanical testing from 1989

TriMed Wrist Fixation System
Design and development, 1994 - present

Patents (issued and pending):

Axial Compression Screw (USA 4628923)
Implantable Surgical buttressing device (USA 5941878)
Asymmetric screw hole angles (USA 6077266)
Pin Plate (USA 5931839)
Locking pin plate (USA 7044951)
Small Fragment Clamp (USA 5709682, Sweden 506462)
L-Plate (USA 5718704, Sweden 505453)
Graft Constraint Devices (USA 6113603)
Sleds (USA 7037708)
Bearing plate (USA appl 20050154392)
Assymetrical buttress pins/post washer (USA appl 20050010228)
Bullet fixation device (USA appl 20050070902)
Sidewinder plate (USA appl not yet assigned)
Trigger knife (USA appl not yet assigned)

(Additional international patents and patents pending)

Societies:

Active:

Hawaii Orthopaedic Association
(President 1993)

Fellow, American Academy of Orthopaedic Surgeons

Miscellaneous:

Honorary Ambassador to Guam
Awarded for crippled children's care
July, 1989

Miscellaneous:

Crippled Childrens field clinics for Shriner's Hospital

Kosrae, Truk, Pohnpei (Federated States of Micronesia)
October, 1995

Saipan, Guam, Palau
June, 1992

Tonga, American Samoa, Western Samoa
May, 1991

Kosrae, Truk, Pohnpei
May, 1990

Saipan, Guam, Palau
July, 1989

Tonga, American Samoa, Western Samoa
July, 1988

Recreation:

Surfing

EXHIBIT II

	PAT. NO.		Title
1	7,749,257	T	Bearing plate for use in fracture fixation having a spherical bearing hole with yielding expandability
2	7,267,678	T	Intramedullary implant for fracture fixation
3	7,195,633	T	Fracture fixation system
4	7,044,951	T	Fracture fixation device in which a fixation pin is axially restrained
5	7,037,308	T	Implant device for applying compression across a fracture site
6	6,113,603	T	Graft constraint device
7	6,077,266	T	Method of enabling bone screws to be installed at an angle in underlying bone
8	5,941,878	T	Implantable, surgical buttressing device
9	5,931,839	T	Pin plate for fixation of bone fractures
10	5,718,704	T	L-shape surgical buttress plate
11	5,709,682	T	Surgical clamp for fixation of bone fragments
12	4,628,923	T	Axial compression device